K061780

510 (k) Summary

SEP 15 2006

Submitter:

Mark Rosoff, President
Rozinn Electronics, Inc.
71-22 Myrtle Avenue
Glendale, NY 11385
Telephone: 718-386-5526
Fax: 718-366-4574
E-mail: mark@rozinn.com
Contact: Mark Rosoff
Date of Summary: June 20, 2006

Name of Device: TTM For Windows +
Common Name: Transtelephonic cardiac monitoring station
Product Code: DXH
Classification name: Telephone electrocardiograph transmitter and receiver.

Substantial Equivalence claimed to legally marketed device:

TTM For Windows + Transtelephonic cardiac monitoring station

Description of Device:

The TTM For Windows + system is designed and manufactured by Rozinn Electronics Inc. It is a PC based computer that is used for Transtelephonic cardiac monitoring. It consists of a standard PC computer, monitor, printer and proprietary download module. . It provides the ability to download, present and store the ECG signal via a phone using commercially available transtelephonic cardiac monitoring devices. TTM For Windows + does not come in contact with the patient. TTM For Windows + does not perform any diagnostic functions. It only presents the data. There is no age or other physiological limitations using this device TTM For Windows +.

Intended use of Device:

The TTM For Windows + is used for Transtelephonic Cardiac Monitoring. It provides the ability to download, present and store the ECG signal via a phone using commercially available transtelephonic cardiac monitoring devices. It only presents the data such as one, two or twelve lead ECG and pacer spikes. There is no age or other physiological limitations using this device TTM For Windows +. It is intended that TTM For Windows + will be used only by a physician and trained technicians. It also acts as a database for patients with or without pacemakers or implantable cardioverter defibrillators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

Rozinn Electronics, Inc.
c/o Mr. Mark Rosoff
President
71-22 Myrtle Avenue
Glendale, NY 11385

Re: K061780
Trade Name: TTM For Windows +
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 20, 2006
Received: June 26, 2006

Dear Mr. Rosoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061780

Device Name: TTM For Windows +

Indications for Use:

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061780

Prescription Use ___X___ AND/OR Over – The – Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)